

FOR COMPLETED STUDIES

Definition:

These clinical trials have completed enrollment, all primary and secondary objectives have been met, and the results published. In the case of a completed study, a written proposal to use the specimens must be submitted for review and approval by NCI/CTEP and review and comment by CTEP’s pharmaceutical collaborator(s) (the supplier of the agents(s) used in the study).

Letter of Support:

The collaborating clinical PI of a completed study should state that the study has been completed, provide a reference for the published study report, and state that remaining biospecimens could be used in collaboration with the applicant. The clinical PI should describe the NCI protocol number, the number and condition of the remaining specimens, and the rationale for consuming them for the proposed studies. The letter should also include the commitment to send a written request for the samples to NCI for review and approval.

FOR ONGOING STUDIES

Definition:

These are clinical trials with a range of statuses, from currently enrolling patients to having completed accrual but not having met all of the study objectives. In the case of ongoing studies, a protocol amendment will be required that will be subject to NCI/CTEP and CTEP’s pharmaceutical collaborator(s) review and approval.

Letter of Support:

The collaborating clinical PI of an ongoing ETCTN study should state a commitment to submit a study amendment to NCI/CTEP to add the proteomic objective to the study (identified by NCI protocol number), and to work with NCI/CTEP to gain approval for the assay. This process would include a determination by NCI/CTEP of whether any of the previously approved objectives have a higher priority that would be compromised by the introduction of a new objective; and a determination of whether the proteomic assay would require review and approval by the CTEP Biomarker Review Committee. The clinical study PI should also describe the number and condition of the biospecimens collected for the study, and the rationale for their use for the proposed studies.

FOR FUTURE STUDIES

Definition:

These are clinical trial proposals that have not yet been reviewed and approved by CTEP.

Letter of Support:

The collaborating clinical PI of a future study should describe the anticipated clinical trial proposal, and how the proteomic analyses will be incorporated as an objective in the study. The clinical study PI should state a commitment to work in collaboration with the proteomics PI to gain CTEP approval of both the objectives and the proposed assay at the time of submission of the Letter of Intent and subsequent protocol to CTEP.